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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/251,638	02/17/1999	HENRY DANIELL	922.6641P	3456

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/251,638

Applicant(s)

DANIELL, HENRY

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003 and 12 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 June 2003 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from ¶10.1, lines 6, 17 and 18, ¶10.2, lines 4-5, ¶10.3, 1-2, 6-11 and 13-15, ¶10.4 (the first one), lines 2-3, and ¶10.4 (the second one), lines 1-4.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

It is noted that 37 CFR 1.52 requires that all papers, other than drawings, that are to become a part of the permanent United States Patent and Trademark Office records in the file of a patent application must be written in a font lettering style having capital letters which are at least 0.21 cm (0.08 inch) high.

Claim Objections

4. Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 already seems to indicate that the pentapeptide is GVGVP; thus claim 10 does not further limit claim 8. The objection is repeated for the reasons of record as set forth in the Office action mailed 10 December 2002, as applied to claim 10.

Applicant's arguments filed 12 June 2003 have been fully considered but they are not persuasive.

Applicant urges that claim 10 has been cancelled (response pg 8).

This is not found persuasive because claim 10 has not been cancelled.

5. Claims 4-5 are objected to because a comma should be inserted after "3" in line 1

Claim Rejections - 35 USC § 112

6. Claims 1, 3-5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 10 December 2002.

Applicant's arguments filed 12 June 2003 have been fully considered but they are not persuasive.

The claims are broadly drawn to multitude of expression cassettes comprising nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once and cotton plants comprising any of a multitude of nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once.

The instant specification, however, only provides guidance for a nucleic acid encoding GVGVPGVGFPGEGFPGVGVPGVGFPGFGFP (paragraph 10.3), which comprises GVGVP twice.

The instant specification fails to provide guidance for nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once or nucleic acids encoding 20-251 repeats of GVGVP.

The specification does not teach how to distinguish synthetic coding sequences from nonsynthetic ones, and does not teach any pentapeptides to be other than GVGVP or VPGVG.

The specification states that one method (particle bombardment) of cotton transformation requires undue experimentation to carry out (pg 6), and the other (Agrobacterium-mediated) can only be carried out on certain cotton cultivars. The specification fails to teach these cultivars.

Given the claim breadth and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once and cotton plants comprising them.

Applicant urges that the inventor has categorized GVGVP in a multitude of different systems and expressed it as a pentapeptide of 20 and 251 repeats. Applicant notes page 1 of the provisional application states that the synthetic sequence for GVGVP was derived from human elastin and the pentapeptide VPGVG (response pg 10).

This is not found persuasive because the specification does not teach a nucleic acid encoding 20-251 repeats of GVGVP, nor does it teach a nucleic acid encoding repeats of any other pentapeptide.

Applicant urges that deposit of plasmid is not necessary (response pg 9).

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It is noted that plasmids pBI121-X2-120mer and pBI121-E6-HW-120mer do not have a fiber-specific promoter, and thus their deposit will not enable any claimed expression cassettes. Thus, Examiner agrees that deposit of these plasmids is not necessary.

7. Claims 1, 3-5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 10 December 2002. Applicant's arguments filed 12 June 2003 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once. In contrast, the specification describes no nucleic acid encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

The specification does not describe the structural features that distinguish synthetic sequences from nonsynthetic ones and does not describe pentapeptides that are repeated at least once within the full scope of the claims.

Hence, Applicant has not, in fact, described nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

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Applicant urges that Fiddes v Baird is factually dissimilar to the instant invention because Applicant's amino acid sequence is a simple pentapeptide repeat of GVGVP, not a complex amino acid like in Fiddes. Applicant urges that they claim a GVGVP that is synthetic (response pg 9-10).

This is not found persuasive because the specification does not describe the structural features that distinguish synthetic sequences from nonsynthetic ones. The specification does not describe pentapeptides that are repeated at least once other than GVGVP and VPGVG.

Applicant urges that the art has far advanced since the filing date for Fiddes (response pg 9).

This is not found persuasive because the codon table was known for about 20 years before the filing of Fiddes and new knowledge about that table has not been added since then.

8. Claims 1, 3, 5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 10 December 2002, as applied to claims 1, 3, 5 and 8.

Applicant's arguments filed 12 June 2003 have been fully considered but they are not persuasive.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "The transgenic cotton plant of claim 1, wherein said gene encodes between 20-251 repeats of the amino acid sequence Gly-Val-Gly-Val-Pro (SEQ ID NO:2)". Thus, such phrases constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrases or to cancel the new matter.

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Applicant urges that support for 20 to 251 repeats of GVGVP is found on pg 2 of the provisional application (response pg 10-11).

This is not found persuasive because while 251 repeats is found on that page, neither 20repeast nor the range 20-251 repeats is found.

9. Claims 1, 3-5 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 10 December 2002. Applicant's arguments filed 12 June 2003 have been fully considered but they are not persuasive.

Claim 1 is indefinite in its recitation of "gene encoding a synthetic coding sequence including at least one pentapeptide". Genes do not encode coding sequences, although they may comprise them. Furthermore, coding sequences are not made up of pentapeptides, although they may encode them. Claim 3 is similarly indefinite in its recitation of "encoding a synthetic coding sequence including at least one pentapeptide".

In claim 3, the placement of all the components relative to one another is not clear.

In claim 4, it is not clear if GVGVP is the pentapeptide encoded in the cassette of claim 3 or if GVGVP is an additional pentapeptide and if that pentapeptide is encoded by the expression cassette or if the peptide is covalently attached to the nucleic acid.

10. Claims 1, 3-5 and 8-10 are free of the prior art, given the failure of the prior art to teach a cotton plant transformed with a gene or coding sequence that encodes a protein comprises at

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least one pentapeptide that is repeated at least once, wherein the gene or coding sequence does not occur in nature and given the failure of the prior art to teach an expression cassette for transformation of such plants, wherein the cassette comprises a fiber-specific promoter.

Conclusion

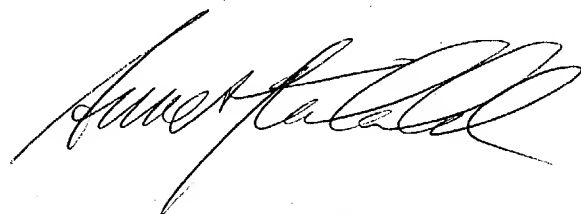
11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 305-3015.

Anne R. Kubelik, Ph.D.
March 29, 2004



**ANNE KUBELIK
PATENT EXAMINER**